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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/954,544	09/12/2001	Henry R. Halperin	212/220	6993

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EXAMINER

DEMILLE, DANTON D

ART UNIT	PAPER NUMBER
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3764

DATE MAILED: 05/04/2004

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/954,544

Applicant(s)

HALPERIN, HENRY R.

Examiner

Danton DeMille

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 February 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- 1) ☐ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. **Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Meister in view of Bastyr et al. and Cantrell et al.**
2. The Meister device is “for producing artificial respiration of persons who have been drowned...” column 1, lines 1-4. The device “is constructed so that the number of impulses or compression-expansion cycles of the device is correct for maximum effectiveness; such timing being difficult to accomplish in manual artificial respiration” column 1, lines 24-30. The device is for patients whose respiration has stopped to maintain proper oxygenated blood. As taught by Cantrell, “Cardio Pulmonary Resuscitation (CPR) is often administered to temporarily sustain blood circulation to the brain and other organs during efforts to re-start the heart pumping” column 1, lines 13-16. This failure of the heart and lungs to work properly can be the result of a drowning column 1, lines 7-9. Both of these references teach that artificial respiration is needed for victims of drowning and Cantrell happens to describe the effort as CPR.
3. It is not clear how much weight can be given the newly added language. The new language describes the controller to contract the band at a sufficient rate to perform CPR and to contract the band to a tightness that is sufficient for CPR. Since Meister already taught a device intended to provide artificial respiration for drowning victims and as taught by Cantrell this functional intended use is CPR, it is not clear how this language has defined over Meister. The Meister device already contracts the band at a rate and tightness sufficient to perform artificial respiration which is CPR. It is maintained that the Meister device is for CPR because both

Meister and Cantrell's teach the same intended use for drowning victims and Cantrell happens to describe this function as CPR.

4. Regarding the language that the controller is "programmed" to control the driver at a rate and tightness sufficient for CPR, Meister teaches an electric motor 20 however, appears silent with regard to how the motor is controlled. The speed of the motor would determine the rate of cyclic pressurization. The computer could also be used to display timing and operational instructions to the user. Programming the driver for periods of application and periods of rest for stimulating the heart are conventional steps in the application of CPR. The benefits of using a computer to control the operation of the device are well known to the artisan of ordinary skill and an obvious provision in Meister. It would have been obvious to one of ordinary skill in the art to modify Meister to provide a computer that can be programmed as suggested by Cantrell to perform the CPR functions of Meister.

5. Meister teaches a band 1, a driver mechanism 6, a cushion 3 and an automatic controller inside the driver mechanism controlling the timing of the compression and expansion cycles. The cushions 3 are attached to the inside surface of the band 1 disposed between the chest of the patient and the band 1. The cushions are located at what would be the sides of the chest of the patient and extend around the chest to the back. The cushions 3 are at least located on the sides of the chest of the patient and therefore comprehend the claimed "disposed between the chest of the patient and the band". Meister appears silent with regard to the details of the cushions 3. It is not clear what is the composition. Bastyr teaches cushion pads 40, 42, 44, 46, 48, 50 that are fluid filled. It would have been obvious to one of ordinary skill in the art to modify Meister to use fluid filled cushions as taught by Bastyr as an obvious equivalent alternative to a foam

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cushion and to provide a soft cushion having a hardness and size that is variable as taught by Bastyr.

6. **Claims 2-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chang in view of Meister and Cantrell et al.**

7. Chang teaches that "It is an aim of the present invention to provide a method and apparatus for providing ventilation by inducing a high frequency vibration or oscillation to the air column in a patient's air way in order to induce artificial breathing and therefore, gas exchange of air, oxygen,..." This is the same purpose of Meister i.e., artificial respiration. This is still another method of increasing air and oxygen exchange into the blood system of an unconscious patient using high frequency oscillations. They are all for the same purpose i.e., artificial respiration and as taught by Cantrell this is called CPR. Therefore all of these devices provide a sufficient rate and tightness to perform CPR. If they didn't then they wouldn't be performing their intended function. As noted before providing a computer in any one of these devices such as Chang would have been an obvious provision as taught by Cantrell to control the operation and provide a informational display would enhance the operation of the device.

8. Chang teaches a band 10 including a plurality of fluid-receiving cells 24, 26, a reciprocating pump for automatically supplying fluid under pressure to the cells. Providing a cushion between the band and the chest of the patient would appear to be well within the realm of the artisan of ordinary skill in order to provide comfort to the patient wherever desired or required. Providing cushions between an apparatus that is intended to squeeze and apply pressure to the patient would be obvious. Meister teaches such a convention in a band adapted to compress the chest and the need for providing compression cushions 3 between the band and the

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chest of the patient. There appears to be no unobviousness to apply cushions between the patient and a band that is being constricted around the chest of the patient dependent on practical considerations. Placing a compressing band around the patient that has local injuries would worsen the injuries and appropriately placed cushions would minimize any further damage to the injury while still allowing compression of the chest for applying artificial respiration. Placing cushions between the band and the chest of the patient would appear to be well within the realm of the artisan of ordinary skill. It would have been obvious to one of ordinary skill in the art to modify Chang to provide compression cushions disposed between the chest of the patient and the band as taught by Meister to protect the chest of the patient from further injury and to enhance the respiration producing action of the device.

9. Regarding claims 3, 6, 9, 12, it would have been obvious to provide a sealed cushion so that moisture from the patient does not saturate the cushion.

10. Regarding claims 5, 8, 11, as shown in the drawing of Chang, the two fluid-receiving cells are in fluid communication with each other because the tubes 30 are linked together. The pressure will always be the same in both cells.

11. **Claims 14, 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baldwin, II in view of Gelfand et al.**

12. Baldwin clearly teaches a device for CPR and a controller 40 for controlling the operation. Gelfand teaches the convention of using a computer that has an algorithm or program to control the pressure and rate of the pressure application. It would have been obvious to one of ordinary skill in the art to modify Baldwin to use a computer as taught by Gelfand to better control the operation of the device.

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13. Broadly, the band 28 of Baldwin extends around the chest of the patient. The piston 18 is operably connected to the band for contracting and expanding the band about the chest of the patient as shown between figures 5 and 6. A fluid filled cushion 32 is disposed between the chest of the patient and the band. An automatic controller 40 controls the operation of the driver mechanism. The cushion 32 is sized and dimensioned to cover substantially the entire anterior and posterior portion of the chest.

14. **Claims 2, 15, 5, 16, 8, 17, 11, 18, 20, 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chang in view of Cook, Cantrell et al. and Bastyr et al.**

15. As noted above, Chang is used for performing CPR as substantiated by Cantrell and to use a controller that is programmed to control the operation of the device such is well within the realm of the artisan of ordinary skill for performing the same functions as suggested by Cantrell.

16. In the art of constricting bands around the chest of patients Cook teaches that for the comfort of the patient cushion 15 is used around the inside of the band. This cushion 15 extends all they way around the inside of the band and therefore would cover substantially the entire anterior portion of the chest of the patient. In the art of providing cushion on the inside of bands adapted to extend around the patient, Bastyr teaches fluid filled cushions are more desirable and an obvious equivalent alternative to foam cushions. It would have been obvious to one of ordinary skill in the art to modify Chang to include a cushion on the inside of the band as taught by Cook for the best comfort for the patient and to use fluid filled cushions as taught by Bastyr as an obvious equivalent alternative to foam.

Response to Arguments

17. Applicant's arguments filed 18 February 2004 have been fully considered but they are not persuasive.

18. Applicant argues that Meister's device is not intended for CPR however this is not true. Meister's device is intended for providing artificial respiration for drowning victims and as taught by Cantrell applying artificial respiration for drowning victims is called CPR.

19. Moreover, it is not clear how the operations would be different. The Meister device is intended to constrict the band around the chest of the patient to stimulate artificial breathing just as applicant's device does. How would it be different?

20. Applicant argues that CPR requires strong, high frequency compressions that provide hemodynamic flow. Cantrell teaches that the heart and lungs stop due to drowning. The compression aid devices are operated to provide artificial respiration in the patient. The compressions have to be strong and high frequency to do this. Both Meister and Cantrell are for providing artificial respirations in drowning victims and both would have to have sufficient strength and high frequency in order to accomplish their objectives. It is not clear how they would be any different.

21. It is not clear how much weight can be given the arguments that the Meister device cannot be used for CPR since would squeeze the sides of the chest which would produce little if any blood flow while anterior-posterior compressions obtained with the claimed device results in significant blood flow. Whether or not the prior art is as efficient as the instant invention is not relevant. The fact that the prior art anticipates the claim limitations is. Meister's device may not be as efficient as applicant's however, Meister teaches at least one "cushion disposed between

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the chest of the patient and the band” as claimed. As pointed out in applicant’s drawings of Meister, the cushions extend from the sides of the patient around to the anterior portion of the chest. In applicant’s view the cushions may not be located about the band of the device for applicant’s best result however, the fact that Meister teaches a cushion that is between the chest of the patient and the band anticipates the claimed limitation even though it may not be located in applicant’s view the most effective location. There are no claim limitations in claims 1-13 that specify any specific placement. The cushions merely have to be between the chest of the patient and the band. Meister’s device clearly anticipates this limitation. Moreover, the exact location of the device during use is dependent on practical considerations of intended use. The Meister device is clearly capable of being placed at any height along the abdomen of the patient. Applicant is merely arguing the exact placement during use.

22. Applicant argues that Meister suggests no other placement of the pads however, this is not true. Meister column 2, lines 1-4 state “[e]ach compression unit [cushion] 2 is longitudinally slidably adjustably secured to the belt 1 by encircling metallic straps 5, whereby said units 2 may be disposed on the belt 1 in proper position”. Clearly, Meister teaches that the placement of the cushions along the band is adjustable so that they can be placed in proper position. Adjusting the placement of the cushions around the chest to achieve the most effective results would be obvious to one of ordinary skill in the art.

23. Applicant also argues that Meister compresses the “abdomen” of the patient however this is not accurate either. Meister (column 1 lines 9-12) teaches the band is “adapted to encircle the chest diaphragm of the person to be treated.” As applicant pointed out Meister would compress the patient’s ribs preferentially with respect to the sternum. This is the chest of the patient. It is

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not clear how applicant can disregard Meister and somehow say this is not the chest of the patient. Again there is no claim language to somehow define over Meister regarding the placement of the band other than about the chest of the patient and clearly Meister anticipates this claim limitation. Again, arguing whether or not the band is placed high enough on the chest of the patient is dependent on intended use. There are no claim limitations that somehow require the band to be placed at a specific location on the patient.

24. Regarding Bastyr, Bastyr is not cited to teach the method of CPR, the primary reference teaches that. Bastyr is cited to teach the convention of using other equivalent cushions for devices intended to clamp around body portions. Protecting the body from devices that are applying compressive pressures on the body require cushions between the device and the body. Meister teaches this and Bastyr teaches this. There is no unobviousness to using any one type of material for the details of construction of the cushion.

25. Applicant also argues that there is no motivation to combine the references. Meister teaches placing cushions between the band and the patient to protect the patient from injury from the band. Bastyr teaches placing cushions between the band and the patient to protect the patient from injury from the band. In the art of providing cushions between the band and the patient to protect the patient from injury clearly a fluid filled cushion is an obvious equivalent alternative to the foam cushions of Meister. It isn't a matter of adding something to Meister. Meister already teaches all of the element claimed. Meister appears silent with regard to the exact details of the cushions 2. It is not clear how Meister makes cushions 2. Bastyr merely provides what Meister lacks. The details of the cushions 2. Bastyr uses fluid filled cushions. Such would have

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been an obvious provision in Meister. It is not an inventive step to replace one type of material for another type of material when both materials are well know obvious equivalents.

26. Applicant's arguments that "Meister provides no indication that adding cushions would work in a CPR device." Applicant's position is not understood since Meister already teaches adding cushions to the device. Meister teaches cushions 2.

27. It is also not clear why applicant argues that "there is no motivation to modify Meister for use as a chest compression device." Meister's device is "for producing artificial respiration of persons who have been drowned or asphyxiated, or whose respiratory systems, because of paralysis, have need of artificial stimulation." It is not clear how applicant can disregard the teaching of Meister.

28. Applicant also argues that Chang's device is placed around the patient's abdomen. Chang clearly teaches that the method of the present invention includes "providing this high frequency ventilation by chest wall compression and expansion, trauma is avoided..." (emphasis added) page 4, lines 18-21. As noted above with regard to Meister, the band of Chang is adapted to go about the chest of the patient just as applicant's invention. Any specific relative positioning of the band about the body of the patient is intended use. Clearly Chang's device is capable of such positioning if not already inherent.

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